

Serial No. 09/777,091

PATENT

CLAIMS

1 1. (Currently Amended) An implantable valve for a bodily passage of
2 tubular shape, comprising:
3 a self-expanding support frame configured for expansion to
4 conform to a wall of the bodily passage, said support frame having a
5 plurality of bends, said plurality of bends configured to provide outward
6 radial force for expansion of said self-expanding frame to anchor the
7 implantable valve to the wall of the bodily passage, said support frame
8 when expanded providing a plurality of side elements each defining a
9 path extending at least partially longitudinally along the wall and at least
10 partially circumferentially around the wall,
11 a plurality of leaflets, each leaflet thereof having a body extending
12 from a wall-engaging outer edge to an inner edge proximate a
13 corresponding inner edge of at least one other leaflet of the plurality of
14 leaflets,
15 the inner edges of said plurality of leaflets cooperable to define an
16 opening therebetween to permit fluid flow in a first direction along the
17 bodily passage, and further cooperable to engage each other sufficiently
18 to restrict fluid flow in a second direction opposing the first direction,
19 the outer edge of each one of the plurality of leaflets attached
20 along one side element of said plurality of side elements and thereby
21 adapted to sealingly engage the wall of the bodily passage in said path
22 extending at least partially longitudinally and at least partially
23 circumferentially such that the leaflet extends along said bodily passage
24 away from the inner edges in said second direction, each of said leaflets
25 thereby forming a curved structure for trapping fluid between the leaflets
26 and the inner wall of the bodily passage in response to fluid flow in said
27 second direction so as to cause said inner edges of said leaflets to
28 engage one another sufficiently to restrict fluid flow in said second
29 direction.

Serial No. 09/777,091

PATENT

1 2. (Currently Amended) The ~~vascular~~ implantable valve of claim 1,
2 wherein at least a portion of the body of the leaflet being flexible at least
3 proximate the free inner edge thereof.

1 3. (Canceled)

1 4. (Currently Amended) The implantable valve of claim 3 1 wherein the
2 outer edges of the plurality of leaflets include overhanging material, the
3 overhanging material extending beyond the frame to which the plurality
4 of leaflets are attached.

1 5. (Currently Amended) The implantable valve of claim 3 1 wherein said
2 frame comprises wire to and around which the bodies of the leaflets are
3 secured.

1 6. (Previously Amended) The implantable valve of claim 1 wherein the
2 plurality of leaflets includes two leaflets such that when the frame is
3 substantially flattened, it assumes a diamond shape with the inner edges
4 of the two leaflets defining a slit therebetween.

1 7. (Original) The implantable valve of claim 3 wherein the body and the
2 frame of each leaflet comprises an integral, one-piece member.

1 8. (Original) The implantable valve of claim 1 wherein said integral, one-
2 piece member is molded into a generally flat shape.

1 9. (Original) The implantable valve of claim 7 wherein said integral, one-
2 piece member is molded into a serpentine shape.

1 10. (Currently Amended) The implantable valve of claim 1 wherein the
2 plurality of leaflets comprises an extracellular collagen matrix.

Serial No. 09/777,091

PATENT

1 11. (Original) The implantable valve of claim 6 10 wherein the
2 extracellular collagen matrix includes small intestinal submucosa.

1 12. (Original) The implantable valve of claim 1 comprising two leaflets.

1 13. (Original) The implantable valve of claim 1 wherein the frame is
2 adapted to assume a plurality of configurations, the plurality of
3 configurations includes a generally flat configuration, whereby the frame
4 in the generally flat configuration is generally diamond-shaped.

1 14. (Canceled)

1 15. (Original) The implantable valve of claim 1 further including at least
2 one barb to anchor the implantable valve to the wall of the bodily
3 passage.

1 16. (Original) The implantable valve of Claim 15 wherein the at least one
2 barb is integral projection extending from the frame.

1 17 - 54 (Canceled)

1 55. (Currently Amended) An implantable valve for a bodily passage of
2 tubular shape, comprising:

3 a support frame configured for expansion to conform to a wall of
4 the bodily passage, said support frame when expanded providing a
5 plurality of side elements each defining a path extending at least partially
6 longitudinally along the wall and at least partially circumferentially around
7 the wall,

8 a plurality of leaflets comprising an extracellular collagen matrix
9 material, each leaflet thereof having a body extending from a wall-
10 engaging outer edge to an inner edge proximate a corresponding inner
11 edge of at least one other leaflet of the plurality of leaflets,

Serial No. 09/777,091

PATENT

12 the inner edges of said plurality of leaflets cooperable to define an
13 opening therebetween to permit fluid flow in a first direction along the
14 bodily passage, and further cooperable to engage each other sufficiently
15 to restrict fluid flow in a second direction opposing the first direction,

16 the outer edge of each one of the plurality of leaflets attached
17 along one side element of said plurality of side elements and thereby
18 adapted to directly engage the wall of the bodily passage therearound
19 and provide ingrowth of adjacent native tissue into the extracellular
 collagen matrix material.

1 56. (New) The implantable valve of claim 55 wherein the collagen matrix
2 material comprises submucosal tissue.

1 57. (New) The implantable valve of claim 55 wherein the collagen matrix
2 material comprises small intestinal submucosa.

1 58. (New) An implantable valve for a bodily passage of tubular shape,
2 comprising:

3 a frame that includes a plurality of legs, each of the legs originating
4 from a pair of bends located about a first end of the implantable valve,
5 and extending in an opposite direction therefrom, each of the plurality of
6 legs terminating at a second end of the implantable valve opposite the
7 first end such that the plurality of legs generally assume a serpentine
8 configuration along the circumference of a bodily passage when situated
9 therein,

10 a plurality of leaflets, each leaflet comprising a covering that
11 includes one or more flexible materials, the leaflet including a body that
12 comprises a wall-engaging outer edge and an inner edge, the outer edge
13 at least partially attached to, and reinforced by one of the plurality of legs,
14 the outer edge and the associated leg adapted to sealingly engage the
15 inner wall of the bodily passage,

Serial No. 09/777,091

PATENT

16 wherein the body of the leaflet extends inward from the wall of the
17 bodily passage and extending toward the first end of the implantable
18 valve where it terminates at the inner edge, the body and inner edge
19 traversing the lumen of the bodily passage when situated therein and
20 being configured such that the leaflet is cooperable with at least one other
21 leaflet to define an opening that permits positive flow of fluid therethrough
22 in a first direction, while the plurality of leaflets are further adapted to trap
23 between the leaflets and the inner wall of the bodily passage fluid flowing
24 in a second direction opposite the first direction and seal against one
25 another to restrict fluid flow in said second direction; and

26 wherein the frame is adapted to assume a plurality of
27 configurations, a first configuration of the plurality of configurations being
28 a generally flat plane.

1 59. (New) An implantable valve for a bodily passage of tubular shape,
2 comprising:

3 a frame that includes a plurality of legs, each of the legs originating
4 from a pair of bends located about a first end of the implantable valve,
5 and extending in an opposite direction therefrom, each of the plurality of
6 legs terminating at a second end of the implantable valve opposite the
7 first end such that the plurality of legs generally assume a serpentine
8 configuration along the circumference of a bodily passage when situated
9 therein,

10 a plurality of leaflets, each leaflet comprising a covering that
11 includes one or more flexible materials, the leaflet including a body that
12 comprises a wall-engaging outer edge and an inner edge, the outer edge
13 at least partially attached to, and reinforced by one of the plurality of legs,
14 the outer edge and the associated leg adapted to sealingly engage the
15 inner wall of the bodily passage,

16 wherein the body of the leaflet extends inward from the wall of the
17 bodily passage and extending toward the first end of the implantable
18 valve where it terminates at the inner edge, the body and inner edge

Serial No. 09/777,091

PATENT

19 traversing the lumen of the bodily passage when situated therein and
20 being configured such that the leaflet is cooperable with at least one other
21 leaflet to define an opening that permits positive flow of fluid therethrough
22 in a first direction, while the plurality of leaflets are further adapted to trap
23 between the leaflets and the inner wall of the bodily passage fluid flowing
24 in a second direction opposite the first direction and seal against one
25 another to restrict fluid flow in said second direction; and

26 wherein the frame is adapted to assume a plurality of
27 configurations, a first configuration of the plurality of configurations being
28 a generally flat plane; and

29 wherein the covering includes two leaflets such that when the
30 frame in the generally flat configuration generally assumes a diamond
31 shape with the inner edges of the two leaflets defining a slit
32 therebetween.

1 60. (New) A valve prosthesis for an implantation in blood vessel,
2 comprising:

3 a support frame including a plurality of bends and interconnected
4 sides, the support frame having a first configuration for intravascular
5 delivery into the blood vessel and a second configuration for
6 implantation therein;

7 a plurality of leaflets, each leaflet having an inner edge and an
8 outer edge;

9 wherein the inner edges of the plurality of leaflets are cooperable
10 with one another to permit blood flow in a first direction within the vein,
11 while restricting blood flow in a second direction opposite the first
12 direction; and

13 wherein the outer edge of each of the plurality of leaflets is
14 attached to at least one of the plurality of interconnected side elements
15 such that the plurality of outer edges engage the walls of the bodily

*FI
Cont*

Serial No. 09/777,091

PATENT

16 passage and collectively form a seal thereagainst along a pathway
17 defined by the plurality of interconnected side elements.

1 61. (New) The valve prosthesis of claim 55 wherein plurality leaflets
2 comprise a bioremodelable material.

1 62. (New) The valve prosthesis of claim 61 wherein the plurality of
2 leaflets comprise an extracellular collagen matrix.

1 63. (New) The valve prosthesis of claim 60, wherein the leaflets form a
2 curved structure for trapping fluid between the plurality of leaflets and
3 the inner wall of the blood vessel in response to fluid flow in the second
4 direction so as to restrict the flow passing through the valve prosthesis
5 in the second direction.

1 64. (New) The valve prosthesis of claims 60, wherein the plurality of
2 bends include at least a first bend and a second bend located about the
3 first end of the prosthesis, the first bend and the second bend
4 interconnecting two of the plurality of sides with two interconnected
5 sides each extending at least partially longitudinally from the first bend
6 and the second bend toward the second end of the prosthesis; and
7 wherein the inner edges of the plurality of leaflets each include a first
8 end and a second end, each of the first and second ends being carried
9 about at least one of the first bend and the second bend.

*F /
Conf*

1 65. (New) The valve prosthesis of claim 64, wherein the first bend and
2 the second bend each carry one of the first end or the second end of
3 each of the plurality of leaflets.